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Rapid HIV Testing Recommended Guidelines

Massachusetts Department of Public Health
February 2007

The development of rapid testing technology to detect HIV infection has created new opportunities for Massachusetts clinical providers and community-based organizations currently offering HIV counseling and testing to increase testing options available to clients. The Clinical Laboratory Program and the HIV/AIDS Bureau of the Massachusetts Department of Public Health (MDPH) have collaborated to develop an advisory on the use of rapid HIV testing in the Commonwealth. The implementation of rapid HIV testing services is a complex process that requires adherence to HIV testing laws and regulations and a commitment to conducting quality control and safety procedures in each testing setting. This advisory explains the regulatory and legal requirements, and programmatic recommendations for conducting rapid HIV tests in Massachusetts.

Certifications and Licensure

The Massachusetts Department of Public Health (MDPH) **recommends** that all agencies and organizations within the Commonwealth of Massachusetts currently offering or seeking to offer rapid HIV tests determine their Clinical Laboratory Improvement Amendments (CLIA) certificate and state licensing status. All such agencies and organizations must complete necessary application forms. In addition, they should review laws and regulations governing HIV testing. Massachusetts General Laws, ch. 111, s. 70f, requires written informed consent prior to HIV testing, independent of the type of HIV test utilized. 105 Code of Massachusetts Regulations 180.000: Rules and Regulations Relating to the Operation, Approval and Licensing of Laboratories Special Requirements – Viral Serology [105 C.M.R 180.300] applies to all sites that conduct any type of HIV testing.

To provide rapid HIV testing in Massachusetts, the following documents **must** be filed with MDPH:

A CLIA Certificate of Waiver, Compliance or Accreditation (must be current)
(see http://www.cms.hhs.gov/forms/cms116.pdf for application);

and one of the following:

A Massachusetts Clinical Laboratory License/Approval, with sub-specialty to perform clinical laboratory testing in Viral/HIV Serology;

or a

Waived HIV Special Projects Waiver Application. Requires response in writing to the Special Project Requirements for Implementation of Rapid (Waived) HIV Tests. The Special Projects Waiver Application is reviewed in consideration of the individualized setting/site.

Completing and signing the above documents affirms a commitment to provide rapid HIV testing and acknowledgement of the Massachusetts Department of Public Health recommendations that all sites offering rapid HIV tests establish written protocols that address the components identified below (1-7).

MDPH is available to provide technical assistance for each level of testing implementation. Please see the Contacts below for information. Additionally, the Clinical Laboratory Program of the Division of Health Care Quality will provide ongoing site-based reviews.

CONTACTS:
CLINICAL LABORATORY PROGRAM: 617-753-8438
HIV/AIDS BUREAU: Joanne de Vries, 617.624.5372, joanne.devries@state.ma.us

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Recommended Guidelines for Rapid HIV Testing in Massachusetts

1. **Informed Consent and Confidentiality**
   Protocols to protect client confidentiality should be written and adhered to in accordance with M.G.L. ch. 111, s. 70F and 105 C.M.R. 180.300 (B) & (C). Policies should define the steps that are in place to maintain confidentiality and privacy throughout the entire testing process: written consent, test performance, disclosure of test results, and storage of records. A specific identifier must be maintained for each specimen tested; however, it does not need to contain the patient name.

2. **Test Procedures**
   a. *Specimen collection and preparation.* Providers should develop written protocols that define: materials and equipment required; steps to follow to perform the test; limitations of the procedure; cautions to be observed which may affect the test results; safety precautions to protect patients and testing personnel; quality control procedures to be followed; and, a plan for remedial or corrective action to be followed in the event that quality control results do not fall within acceptable limits.

   b. *Follow-up Testing.* All "non-negative/reactive" rapid test results require confirmation through submission of a serum specimen. Regardless of the licensed clinical laboratory identified for submission, the specimen should be flagged as confirmatory and have a Western Blot or immunofluorescence assay (IFA) test performed, regardless of any enzyme immunosorbent assay (EIA) result.

   c. *Reagents.* Providers should store and dispose of all reagents properly (reagents cannot be used beyond their expiration dates). A documentation system should be maintained for lot numbers, date of receipt, record of storage temperatures, expiration date, and dates in use. Manufacturer's directions should be followed regarding the expiration date of "opened" reagents. Reagents from kits with different lot numbers should not be used interchangeably.

3. **Quality Control Procedures**
   a. *Test Procedures.* Providers should develop procedures that outline the specific steps required to perform the test correctly; how to interpret both patient and internal/external control results; actions to be taken when results are not acceptable; and, documentation of required data.

   b. *Controls.*

      i. Under 105CMR.030.D4 ("each qualitative method must be tested with a positive and negative control on each day of testing"), positive internal control and negative external control must be run on each day of testing.

      ii. *External Positive Controls.* Positive controls for HIV-1 and HIV-2 should be run on a weekly basis. Given the substantial burden associated with recalling patients

in the event of a failed external control, individual sites may choose to run the external controls on a more frequent basis. These external controls are weakly reactive (compared to the internal control) and provide important additional information about test performance.

iii. Providers should document that controls have been run, noting the date, type of control, control test results, control lot number, and control expiration date.

c. *Outside Review.* The Clinical Laboratory Program of the Division of Health Care Quality at 99 Chauncy Street, Boston will provide ongoing site-based reviews.

4. Safety
   a. *Storage and Disposal.* Providers should develop storage and disposal procedures for all infectious or physically dangerous medical waste, including blood stained materials in accordance with the following State and Federal regulations:
      i. Storage and Disposal of Infectious or Physically Dangerous Medical or Biological Waste State Sanitary Code Chapter VII [105 C.M.R. 480.000]
      ii. OSHA Blood Borne Pathogen Regulations [29 C.F.R. 1910.1030]
   b. *Sanitization of Physical Space.* Providers should develop procedures to disinfect the testing area appropriately on each day of testing.
   c. *Protective Equipment* . Providers should acquire, store and utilize appropriate personal protective equipment for collecting specimens or performing tests. This equipment includes safety goggles, gloves, absorbent workspace covers, splash guards, sharps disposal container, biohazard waste container, and any other apparatus required at the individual site.
   d. *Specimen Collection.* Providers should develop training and procedures to indicate blood collection is done in an aseptic manner so as to protect both the patient and the testing personnel. Training for proper capillary blood collection techniques should be documented.

5. Program Components
   a. *Pre- and Post-Test Counseling*. Providers should consistently adhere to pre-test and post-test counseling protocols (see *MDPH HIV Counseling & Testing: Core Standards and Practice,* Fall 2003). Assessment of readiness to test and informed consent must be conducted prior to specimen procurement; other aspects of pre-test counseling may be conducted during the testing period. Protocols should include policies and procedures to address receipt of rapid results and confirmatory testing follow-up if the rapid test is reactive.
   b. *Integration of Rapid Tests.* All providers who receive funding from the MDPH HIV/AIDS Bureau to provide HIV Counseling, Testing & Referral services (serum specimen and/or OMT) must integrate HIV rapid tests into the established program.
   c. *Referrals to Care and Support Services*. Providers should develop referral and linkage processes. These should include links to case management services, primary health care, follow-up testing (if not available on-site), needle exchange and other services. (http://www.mass.gov/dph/aids/hivaids.htm)

6. Records
   a. *Test/Reagent Data*. Providers should document all test/reagent data. These data should include but are not limited to: lot number, record of reagent storage temperatures; date and time of specimen collection; time test device was inserted into the developer solution; time result was read; temperature in the room when the test was performed; test result;

quality control results; who performed the test, test kit storage logs and confirmatory result logs.

b. *Confirmatory Testing.* Providers should indicate in records that confirmatory serum testing was performed on all "non-negative/reactive" patient specimens.

c. *Discordant Results.* Providers must consult with MDPH on appropriate state and federal guidelines for the reporting of discordant results. Current CDC guidelines state that if confirmatory testing yields either negative or indeterminate results, follow-up testing should be performed on a blood specimen collected 4 weeks after the initial reactive HIV rapid test result (CDC-NCHSTP-DHAP: Rapid HIV Testing).

d. *Maintenance.* Providers should maintain all records for at least four (4) years, or according to CLIA certificate (whichever is longer).

7. Personnel

a. *Qualifications.* Providers should identify and document qualifications and training needs of personnel performing rapid HIV testing. Training should be inclusive from specimen collection to test reporting (including, but not limited to, technical procedures, quality control requirements, competency testing).

b. *Proficiency.* Providers should demonstrate and document ongoing competency on a yearly basis. Documentation will be examined by Clinical Laboratory Program staff during on-site reviews. Quality assurance and training measures must be established for staff who fail competency and proficiency procedures.

When to run External Controls

1. **External controls must be run at periodic intervals as dictated by the Massachusetts HIV Special Waiver Standards document (daily for HIV negative controls, weekly for HIV-1 and HIV-2 positive controls).**
    - Given the substantial burden associated with recalling patients in the event of a failed external control, individual sites may choose to run the external controls on a more frequent basis. These external controls are weakly reactive (compared to the internal control) and provide important additional information about test performance.
    - If the controls produce the expected result (the HIV-1 positive control is positive, the HIV-2 positive control is positive, and the negative control is negative) continue with patient testing.
    - If they do not produce the expected result repeat the external controls.
    - If they still do not produce the expected results DO NOT proceed with patient testing and contact OraSure Technologies Customer Service (800-869-3538) and notify Arthur Kazianis, HIV Laboratory Supervisor at the State Lab (617-983-6372).
2. **Each new operator must first successfully run OraQuick ADVANCE using the External controls before they are allowed to test patient specimens.**
3. **External controls must be run each time a new lot number is opened.**
    - Use only one lot number at a time. If the controls produce the expected result (the HIV-1 positive control is positive, the HIV-2 positive control is positive, and the negative control is negative) continue with patient testing.
    - If they do not produce the expected result repeat the external controls.
4. If they still do not produce the expected results DO NOT proceed with patient testing and contact OraSure Technologies Customer Service (800-869-3538) and notify Arthur Kazianis, HIV Laboratory Supervisor at the State Lab (617-983-6372).

5. **External controls must be run on all new shipments that are received, even if it is the same lot number that is currently in use. If the shipment contains more than one lot number the external controls must be run on each lot number.**
    - If the controls produce the expected result (the HIV-1 positive control is positive, the HIV-2 positive control is positive, and the negative control is negative) kits are okay for storage.
    - If they do not produce the expected result repeat the external controls.
    - If they still do not produce the expected results DO NOT use the kits in the new shipment for patient testing and contact OraSure Technologies Customer Service (800-869-3538) and Arthur Kazianis, HIV Laboratory Supervisor at the State Lab (617-983-6372).
    - If this shipment is a new lot # and will not be used right away for patient testing, the external controls must be run again prior testing patient samples. If this shipment is a new lot # and will be used right away for patient testing, the external controls do not have to be re-run prior to testing patient samples.
6. **External controls must be run when the temperature of the test kit storage area falls below 2°C (35°F) or rises above 27°C (80°F).**
    - If the controls produce the expected result (the HIV-1 positive control is positive, the HIV-2 positive control is positive, and the negative control is negative) continue with patient testing.
    - If they do not produce the expected result repeat the external controls.
    - If they still do not produce the expected results DO NOT proceed with patient testing contact OraSure Technologies Customer Service (800-869-3538) and notify Arthur Kazianis, HIV Laboratory Supervisor at the State Lab (617-983-6372).
7. **External controls must be run when the temperature of the testing area falls below 15°C (59°F) or rises above 37°C (99°F).**

- If the controls produce the expected result (the HIV-1 positive control is positive, the HIV-2 positive control is positive, and the negative control is negative) it is okay to run patient samples at the current temperature of the testing area for a limited time (i.e. the rest of the day).
- If they do not produce the expected result repeat the external controls.
- If they still do not produce the expected results DO NOT proceed with patient testing and contact OraSure Technologies Customer Service (800-869-3538) and notify Arthur Kazianis, HIV Laboratory Supervisor at the State Lab (617-983-6372).

8. **External controls must be run if you receive two consecutive invalid test results on a patient.**
   - If the controls produce the expected result (the HIV-1 positive control is positive, the HIV-2 positive control is positive, and the negative control is negative) continue with patient testing.
   - If they do not produce the expected result repeat the external controls.
   - If they still do not produce the expected results DO NOT proceed with patient testing and contact OraSure Technologies Customer Service (800-869-3538) and notify Arthur Kazianis, HIV Laboratory Supervisor at the State Lab (617-983-6372).
9. **If operator tests at more than one site, external controls must be successfully run at the additional site before the operator can begin testing at that site.**

OraQuick Rapid HIV-1 Antibody Test- When to run external controls
1. Each new operator must first successfully run OraQuick using the external controls before they are allowed to test patient specimens. 2. External controls must be run at periodic intervals as dictated by the user facility (negative external control daily and positive external controls for HIV-1 and HIV-2 weekly) 3. External controls must be run on all new shipments that are received prior to use, even if it is the same lot number that is currently in use. 4. External controls must be run when the temperature of the test kit storage area falls below 2°C (35°F) or rises above 27°C (80°F).

5. External controls must be run when the temperature of the testing area falls below 15°C (59°F) or rises above 27°C (80°F).

6. External controls must be run each time a new lot number is opened. (Use only one lot number at a time)

7. External controls must be run if you receive two consecutive invalid test results on a patient.

8. If operator tests at more than one site, external controls must be successfully run at the additional site before the operator can begin testing at that site.